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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,922	04/07/2004	David Y. Chien	PP-01445.007	8753

27476 7590 05/12/2005

Chiron Corporation
Intellectual Property - R440
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EXAMINER

MOSHER, MARY

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/820,922

Applicant(s)

CHIEN ET AL.

Examiner

Mary E. Mosher, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/19/04, 7/22/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 July 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/22/04</u> . | 6) <input type="checkbox"/> Other: _____ |

25

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,815,160. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to embodiments of the previously claimed subject matter, which are identified as preferred embodiments in the disclosure supporting the patent claims. Preferred embodiments are obvious species within the scope of the previously patented generic claims.

Allowable Subject Matter

Claims 1 and 3-14 are allowable, subject to resolution of the double patenting issue.

The following is a statement of reasons for the indication of allowable subject matter: For claims 1 and 3-9, Cardoso et al is cited as the closest prior art, as in the

parent application. Cardoso teaches contacting a sample with an anti-human antibody and a monoclonal hepatitis C virus envelope protein antibody in an immunofluorescence assay, but does not teach or suggest using an anti-human IgG Fc antibody attached to a solid phase.

For claims 10-14, prior art such as Maertens et al WO 99/24054 teaches an assay for detecting human anti-E1/E2 antibodies using a labeled anti-human IgG Fc, and an assay for detecting E1/E2 proteins using monoclonal antibodies; see page 21 for example. However, Maertens does not teach or suggest a kit combining anti-human IgG Fc with labeled anti-E1 or anti-E2 monoclonal antibody.

Patents such as Persson et al (WO 97/40176) suggest an assay for detecting HCV env antigen or virions using anti-env monoclonal antibodies, but do not teach or suggest using an anti-human IgG Fc antibody in addition. Chien et al (WO 99/15898) teach an antigen-capture assay for HCV antigen using anti-human antibodies, but do not teach or suggest using an anti-env monoclonal antibody in addition. Reesink et al (Dev. Biol. Stand. 81:77-84, 1993) and Deleersnyder et al (Journal of Virology 71:697-704, 1997) indicate that those skilled in the art believed that detection of HCV antigens was difficult, because of low levels of HCV particles in samples. The review by Pawlotsky (Journal of Hepatology 31 (Suppl.1): 71-79, 1999) indicated knowledge of an assay for detecting HCV core antigen, but that the assay was less sensitive than other existing assays. Aoyagi et al (J. Clin. Microbiol. 37:1802-1808, 1999) teach a more sensitive assay for detecting HCV core antigen, but teach destruction of the endogenous bound human antibodies with heat and detergent before assay, not

detection with added anti-human antibodies. Taken together, the art as a whole does not provide adequate motivation to combine the disparate elements of anti-human IgG Fc antibodies and anti-env monoclonal antibodies in a diagnostic assay for detecting hepatitis C virus in a suspect sample, with reasonable expectation of success.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

5/11/05


MARY E. MOSHER, PH.D.
PRIMARY EXAMINER